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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/619,285	07/19/2000	Jeno Gyuris	MIV-109.01	2224

28120 7590 09/26/2002

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BOSTON, MA 02110-2624

EXAMINER

DAVIS, NATALIE A

ART UNIT	PAPER NUMBER
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1642

DATE MAILED: 09/26/2002

15

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/619,285

Applicant(s)

GYURIS ET AL.

Examiner

Natalie A. Davis

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) 1-27 and 35-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-34 and 49-79 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

1. Applicant's response sent 5 July 2002 is acknowledged. Accordingly, claims 28-34 and 49- 79 are under examination.

Response to Arguments

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Information Disclosure Statement

3. The information disclosure statement has been considered. A signed copy is attached hereto.

Specification Objection Maintained

4. Objection to the disclosure is maintained because the amino acid residues of serum albumin loop regions, for example on page(s) 35-36, in the specification have not been amended to include a sequence identifier.

Claim Rejections - 35 USC § 112 2nd Withdrawn

5. Rejection of claims 28-34 and 49-79 under 35 U.S.C.112, second paragraph is withdrawn in view of explanation. However, the claims are objected to see below.

New Claim Objections

6. Claims 28-34 and 49-79 are objected to because the claims do not have sequence identifiers for the amino acid residues in the cysteine loop. Applicants indicate that figure 1 illustrates the 3-D space-filling model of human serum albumin. As the protein sequences are highly conserved and a skilled artisan would readily understand that "residues 360-369" refers to mature serum albumin. However, all non-D amino acid sequences with four or more specifically defined amino acids must be referenced by sequence identifiers. Correction is required.

Claim Rejections - 35 USC § 112 1st Maintained

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7. Rejection of claims 28-34 and 49-79 under 35 U.S.C.112, first paragraph is maintained for reasons set forth in the previous office action. The traversal is on the grounds that serum albumin serves as a protein carrier and any nucleic acid encoding a peptide sequence published in literature to have activity may be used in the invention. There is no specific requirement for a particular biological activity, as long as the heterologous peptide has at least one biological activity. Applicant's arguments have been considered but are not persuasive because the specification (page 8) states that the heterologous peptide sequence shares less than 40% identity with a sequence to which it is compared. The claims are drafted do not indicate what sequence the heterologous peptide insert is to be compared to; thus, one of ordinary skill in the art would not know which heterologous peptide insert to select for to use in the invention as claimed.

Claim Rejections - 35 USC § 112 1st Withdrawn

8. Rejection of claim 58 under 35 U.S.C.112, first paragraph is withdrawn in view of arguments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natalie A. Davis whose telephone number is 703-308-6410. The examiner can normally be reached on M-F 8-5:30 (every other Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa PhD can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4315 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Natalie A. Davis, PhD
September 24, 2002


SHEELA HUFF
PRIMARY EXAMINER